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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/790,027	03/02/2004	John A. Giordano	48508-00014	9737

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EXAMINER

CHOI, FRANK I

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 09/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/790,027

Applicant(s)

GIORDANO ET AL.

Examiner

Frank I. Choi

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 August 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 187-201 and 217-231 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 187-201 and 217-231 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The rejections of claims 187, 190, 193, 195-201 as being anticipated by Nidamarty et al. (US 2003/0206969) under 35 U.S.C. 102(e) and of claims 187-201, 217-231 as being unpatentable over Nidamarty et al. (US 2003/0206969) under 35 U.S.C. 103(a) are withdrawn solely for the following reasons:

Applicant argues that Nidamarty et al. does not claim the “same patentable invention” as claimed by Applicant because Applicant’s claims include the limitation “free of any other added minerals and any other added vitamins”. However, Claims 36 and 38 expressly disclose embodiments which do not contain any other added minerals or other added vitamins. Examiner notes that there was no disclosure in Applicant’s Specification which explicitly set forth that the claimed composition was “free of any other added minerals and any other added vitamins”. However, it would be readily apparent and one of ordinary skill in the art could immediately envisage a composition which did not contain any other added minerals or any other added vitamins from the original disclosure. For the same reasons, it would be readily apparent and one of ordinary skill in the art would immediately envisage from the claim 36 and 38 in Nidamarty et al., a composition which contains only the vitamins and minerals which are explicitly claimed therein. Further, Nidamarty et al. does not teach away from the claimed composition as paragraph 0062 only discloses that additional vitamins and minerals may be combined with ferrous bisglycinate chelate and ferrous fumarate. This does not preclude claims 36 and 38 from disclosing an embodiment which contains only the vitamins and minerals explicitly disclosed therein and, thus, does not constitute a teaching away from a composition which only contains the vitamins and minerals explicitly set forth in the claims. Examiner notes that Applicant’s Specification discloses the use of “one or more vitamins” and that the

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compositions "may comprise or use a combination of vitamins and minerals" (Specification, paragraphs 0018, 0048). As such, Nidamarty et al. does not teach away from the claimed invention any more than would Applicant's Specification teach away from the claimed limitation above. If Applicant's arguments were valid, Applicant's own claims would be deficient under 35 USC 112, 1st paragraph, for said limitation.

Notwithstanding the same, the Rule 131 affidavit will be entered and accepted with the understanding that this does not preclude the Office from later declaring an interference, if necessary.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 187-201, 217-231 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4 of US Pat. 6,814,983. Although the conflicting claims are not identical, they are not patentably distinct from each other because they both set forth compositions containing the same vitamins and minerals with claims 1-4 of said US Patent anticipating claims 187, 217 by claiming amounts which are encompassed by the scope of the claims 187,217.

The difference between the claims of the '445 patent and the claimed invention is that said claims do not expressly disclose the specific forms of Vitamin A, Vitamin D, Vitamin E, Vitamin B1, Vitamin B6, niacin, calcium, iron, magnesium, zinc, and copper set forth in the dependent claims 188, 189, 191, 192, 194, 196, 197-201, 218, 219, 221, 222, 224, 226-231.

However, the prior art amply suggests the same as Vitamin A, Vitamin D, Vitamin E, Vitamin B1, Vitamin B6, niacin, calcium, iron, magnesium, zinc, and copper are disclosed in the '445 patent. As such, it would have been well within the skill of and one of ordinary skill in the art would have been motivated to use any pharmaceutically acceptable form or equivalent form of vitamins and minerals set forth in claims 1-4 of said US patent with the expectation that the same would be suitable as a nutritional supplement.

Examiner has duly considered Applicant's arguments but deems them unpersuasive.

Applicant must traverse and/or file an amendment which avoids the double patenting rejection or file a terminal disclaimer. Applicant does not cite to any authority, statute, rule, MPEP section or caselaw, which would require the abeyance of a double patenting rejection under the circumstances herein. If Applicant defers in addressing the double patenting issue as indicated then the rejection must be maintained.

Therefore, the claimed invention, as a whole, would have been obvious modification of the claims of the '445 patent to one of ordinary skill in the art at the time the invention was made, because every element of the invention has taught by the teachings of said claims.

Claims 187-201, 217-231 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4 of US Pat. 6,814,983 in view of Manning et al. (US Pat. 6,569,445) or Nidamarty et al. (US 2003/0206969).

Claims 1-4 disclose a composition comprising Vitamin A, Vitamin D, Vitamin C, Vitamin E, folic acid, Vitamin B1, Vitamin B2, Vitamin B6, Vitamin B12, niacin, calcium, iron, magnesium, zinc, and copper, wherein said composition is administrable to a patient, and wherein said composition is free of any other added minerals and any other added vitamins.

Manning et al. discloses that the use of vitamins and minerals such as beta-carotene, cholecalciferol, ascorbic acid, dl-alpha-tocopheryl acetate, thiamine mononitrate, riboflavin, pyridoxine hydrochloride, cyanocobalamine, niacinamide, calcium carbonate, ferrous fumarate, magnesium oxide, zinc oxide, cupric oxide as a dietary supplement (Manning et al., Column 7, lines 60-68, Column 8, Column 9, lines 1-10

Nidamarty et al. discloses a composition containing Vitamin A (about 0.002 mg to about 15 mg), Vitamin D (about 0.001 mg to about 0.6 mg), Vitamin C (about 10-1000 mg), Vitamin E (about 1 mg to about 125 mg), Vitamin B1 (about 0.5-50 mg), Vitamin B2 (about 0.5-50 mg), Vitamin B6 (about 0.1-200 mg), Vitamin B12 (about 2 -250 mcg), niacinamide (about 1-100 mg), calcium (calcium carbonate) (about 20-1000 mg, about 80-110 mg, 100 mg), iron (ferrous fumarate) (about 10-200 mg), magnesium oxide (about 0.1-400 mg), zinc oxide (about 5-100 mg) and cupric oxide (about 0.1-10 mg) as a dietary supplement (Nidamarty et al., Claims 35,36,38).

The difference between the claims of the '445 patent and the claimed invention is that said claims do not expressly disclose the specific forms of Vitamin A, Vitamin D, Vitamin E, Vitamin B1, Vitamin B6, niacin, calcium, iron, magnesium, zinc, and copper set forth in the dependent claims 188, 189, 191,192, 194, 196, 197-201, 218, 219, 221, 222,224, 226-231. However, the prior art amply suggests the same as Vitamin A, Vitamin D, Vitamin E, Vitamin B1, Vitamin B6, niacin, calcium, iron, magnesium, zinc, and copper are disclosed in the '445

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patent. As such, it would have been well within the skill of and one of ordinary skill in the art would have been motivated to use any pharmaceutically acceptable form or equivalent form of vitamins and minerals set forth in claims 1-4 of said US patent with the expectation that the same would be suitable as a nutritional supplement.

Examiner has duly considered Applicant's arguments but deems them unpersuasive for the same reasons as above.

Therefore, the claimed invention, as a whole, would have been obvious modification of the claims of the '445 patent to one of ordinary skill in the art at the time the invention was made, because every element of the invention has taught by the teachings of said claims.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

A facsimile center has been established in Technology Center 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier number for accessing the facsimile machine is 571-273-8300.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Choi whose telephone number is (571)272-0610. Examiner maintains a flexible schedule. However, Examiner may generally be reached Monday-Friday, 8:00 am – 5:30 pm (EST), except the first Friday of the each biweek which is Examiner's normally scheduled day off.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Mr. Gary Kunz, can be reached at 571-272-0887. Additionally, Technology Center 1600's Receptionist and Customer Service can be reached at (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

FIC

September 13, 2005



JOHN PAK
PRIMARY EXAMINER
GROUP 1600